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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Friedel Frauendorfer
Application No.:	09/719258
Filed:	April 13, 2000
For:	ORAL DOSAGE FORM
Examiner:	Sharmila S. Gollamundi
Group Art Unit:	1616
Firm Docket No.:	H01.21-9587-US01

## MAIL STOP APPEAL BRIEF-PATENTS

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Respectfully submitted,  
VIDAS, ARRETT & STEINKRAUS

Date: December 1, 2004

By: \_\_\_\_\_

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Mary C. Granger

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Docket No.: H01.2I-9587-US01

## REPLY BRIEF ADDRESSING NEW GROUNDS OF REJECTION

This Brief is filed under 37 CFR § 41.41 in reply to the Examiner's Answer mailed October 1, 2004. This Brief addresses the new grounds of rejection raised in the Examiner's Answer. Appellant hereby requests that the Appeal be maintained.

**(i) Real Party in Interest**

The Application is assigned to Meduna Arzneimittel GmbH, a corporation having its principal place of business at Ernst-Grote-Strasse 23, D-30916 Isernhagen/Germany.

**(ii) Related Appeals and Interferences**

No related appeals or interferences are pending.

**(iii) Status of Claims**

Claims 1 – 14 stand rejected and are the subject of this appeal. No other claims are pending. Claims 1-7 and 12-14 were rejected under new grounds of rejection in the Examiner's Answer and will be addressed in this Reply Brief.

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**(iv) Status of Amendments**

No Amendment has been filed subsequent to the Final Office Action dated 10/29/03.

**(v) Summary of Claimed Subject Matter**

The present invention relates to an oral dosage form for food, food supplements and dietics (see page 1, lines 1 – 2). For example, the oral dosage form provides positive effects for the metabolism of fat and intestinal inflammations (see page 3, lines 19 – 21).

In one embodiment, the invention comprises polyunsaturated fatty acids in a gelatine capsule, the gelatine capsule being xylose-hardened to an extent sufficient to inhibit peroxidation of the polyunsaturated fatty acids (see page 2, lines 11 – 12 and 17 – 19). Because peroxidation of the polyunsaturated fatty acids is inhibited by the xylose-hardened capsule, antioxidants are not required to be mixed into the fatty acids (see page 2, lines 14 – 16). The Application provides tables comparing the peroxide values at given time intervals between xylose-hardened and non-hardened 500 mg perilla oil capsules (see page 4).

Polyunsaturated fatty acids may include omega-3 polyunsaturated acids with a high content of alpha linolenic acid, such as perilla oil; fish oil; linseed oil; and gamma-linolenic acid. (see page 3, lines 4 – 6).

Xylose-hardening provides the gelatine capsule with a retarded opening time of 45 minutes or more (see page 2, lines 12 – 13). By providing an undisturbed release of the polyunsaturated fatty acids in the intestine after passing the stomach, unpleasant smells and flatulence may be prevented (see page 2, lines 20 – 22).

Xylose-hardening of the gelatine capsule may be achieved by spraying the capsule with a solution comprising xylose, ethanol and water for a predetermined time interval. The capsules may be heated during spraying. After spraying, the capsules may be heat-treated for a predetermined time interval, causing the xylose to react with the gelatin to provide a cross-linking (see page 4, lines 2 – 9).

**(vi) Grounds of Rejection to be Reviewed on Appeal**

Issues 1 and 2 were discussed in the Appeal Brief filed July 8, 2004.

Issue 3: Whether claims 1-7 and 12-14 are patentable under 35 USC § 103(a) over EP

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0240581 to Flacher in view of Buser et al. (US 5948818; hereinafter "Buser").

(vii) **Argument**

**Issue 3: Whether claims 1-7 and 12-14 are patentable under 35 USC § 103(a) over EP 0240581 to Flacher in view of Buser (US 5948818).**

Appellant asserts that a prima facie case of obviousness has not been established because Flacher in view of Buser do not teach all of the limitations of the rejected claims. Further, the Examiner has impermissibly relied on possible inherency and hindsight in making the rejections under 35 USC § 103.

Appellant asserts that neither Flacher nor Buser teaches "a gelatine capsule being xylose-hardened to an extent sufficient to inhibit peroxidation of polyunsaturated fatty acids" as recited in independent claim 1.

Flacher discloses gelatin capsules but does not discuss polyunsaturated fatty acids or the peroxidation of polyunsaturated fatty acids. Flacher is silent as to peroxidation in general.

Buser teaches polyunsaturated acids and a problem of oxidation of the polyunsaturated acids, but solves the problem using chemical antioxidants. See column 3, lines 36-41.

The applied prior art does not establish that a xylose hardened gelatin capsule is capable of inhibiting the peroxidation of fatty acids. The Examiner has provided no rationale, other than Appellant's own disclosure, which suggests that a xylose hardened gelatin capsule can inhibit peroxidation of its contents. *The Examiner has not provided any extrinsic evidence that a xylose hardened gelatin capsule inherently inhibits peroxidation of polyunsaturated fatty acids.*

The prior art itself, and not the applicant's achievement, must establish the obviousness of the combination. Nothing in the prior art suggests that the Flacher gelatin capsules are capable of inhibiting peroxidation of polyunsaturated acids contained within the capsules. Therefore, Appellant asserts that a prima facie case of obviousness has not been established with respect to claim 1. Dependent claims 2-6 and 12-14 depend from independent claim 1 and are not unpatentable for at least the reasons discussed with respect to claim 1. Accordingly, Appellant requests reversal of the rejections.

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**Dependent claim 6**

In addition to the arguments previously presented, Appellant asserts that claim 6 requires the absence of antioxidants.

Buser teaches the use of chemical antioxidants to inhibit oxidation of polyunsaturated acids. See column 3, lines 36-41. Flacher is silent as to oxidation in general and simply discloses a gelatin capsule.

Because Flacher does not mention inhibition of oxidation, a person of ordinary skill in the art using Buser's polyunsaturated acids with Flacher's gelatin capsule would be motivated to also include Buser's antioxidants. Therefore, Flacher in view of Buser teaches away from claim 6. The Examiner has not shown any prior art motivation to remove the antioxidants from Buser. Accordingly, Appellant requests reversal of the rejection.

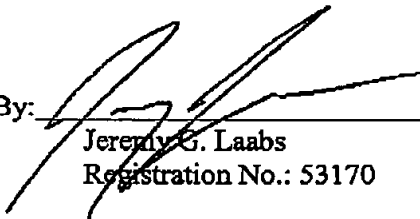
**Dependent claim 7**

Dependent claim 7 has been rejected under 35 USC § 103(a) Flacher in view of Buser. However, dependent claim 7 depends from independent claim 11, which has not been rejected. Therefore, Appellant requests reversal of the rejection.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: 12/1, 2004

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**(ix) Claims Appendix**

1. An oral dosage form for food, food supplements and dietetics comprising polyunsaturated fatty acids in a gelatine capsule, the gelatine capsule being xylose-hardened to an extent sufficient to inhibit peroxidation of polyunsaturated fatty acids.
2. The dosage form as recited in claim 1 comprising omega-3 polyunsaturated fatty acids with a high content of alpha linolenic acid.
3. The dosage form as recited in claim 1, wherein said gelatine capsule has a retarded release time of more than 45 minutes.
4. The dosage form according to claim 1, wherein said dosage form is operative against diseases of metabolism of fat and/or against intestinal inflammations.
5. The dosage form according to claim 1, wherein the gelatine capsule comprises one ingredient selected from the group consisting of fish oil, linseed oil and gamma linolenic acid.
6. The dosage form according to claim 1, wherein no antioxidants are added to the polyunsaturated fatty acids.
7. The method as recited in claim 11, wherein said gelatine capsule comprises polyunsaturated fatty acids with a high content of alpha linolenic acid.
8. The method as recited in claim 7, wherein said gelatine capsule comprises perilla oil.
9. The method according to claim 11, wherein said gelatine capsule has a retarded release time of more than 45 min.
10. The method according to claim 11, wherein said gelatine capsule comprises an ingredient selected from the group consisting of fish oil, linseed oil and gamma linolenic acid.

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11. A method for slowing down peroxidation of polyunsaturated fatty acids used for food, food supplement and dietetics comprising the step of utilizing a gelatine capsule, the gelatine capsule being xylose-hardened to an extent sufficient to inhibit peroxidation of polyunsaturated fatty acids.

12. The dosage form as recited in claim 1, wherein the gelatine capsule is formed by a process including spraying the capsule with xylose.

13. The dosage form as recited in claim 12, wherein the process further comprises heat treatment for a predetermined time interval.

14. The dosage form as recited in claim 13, wherein the process further comprises a reaction between the xylose and gelatine capsule to provide a cross-linking.